



**caBIG Workspace and Working Group Kickoff Meeting
Strategic Level Working Group – Data Sharing and Intellectual Capital
Meeting February 19, 2004 (1.30p.m. – 4.30p.m.)**

Grand Hyatt Washington

Agenda

Facilitator: Wendy Patterson, Esq.

1:30 pm	Welcome and Introductions	Ken Buetow
1:45 pm	Overview of Working Group Roles and Charters	Wendy Patterson
2:15 pm	Discussion Sessions – Group Focus and Goals	Wendy Patterson
4:30 pm	Adjourn	

Summary

Group participants discussed the following topics in the Data Sharing and Intellectual Capital Strategic Level Working Group breakout session:

- Definition of the caBIG program data context
- Potential constraints to sharing of data and intellectual capital
- What data needs to be shared
- Identify issues/solutions that must be addressed
- The need for industry collaboration
- Propose a cancer community cultural standard
- Privacy issues and patient consent
- The identification and inclusion of additional caBIG participants



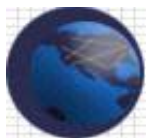
Summary

Urgent action items:

Person responsible:

Deadline:

- 1) Actions related to internal communication and collaboration.
- 2) Mechanisms for internal group coordination and communication.
- 3) Establishing a next meeting of the Data Sharing group.



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NOTES

Facilitator – Wendy Patterson, Esq.

Logistics Support – Douglas Tidquist, caBIG Program Staff

Materials: Sign In Sheets; caBIG Strategic Groups: Overview and Scope Handout; caBIG Strategic Level Working Group Training: Breakout Discussion Handout; Charters Handout.

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Structure of Session

Agenda		
1:30 pm	Welcome and Introductions	Ken Buetow



1:45 pm	Overview of Working Group Roles and Charters	Wendy Patterson
2:15 pm	Discussion Sessions – Group Focus and Goals	Wendy Patterson
4:30 pm	Adjourn	



Session Discussion Points Raised by Participants

Area 1 – Definition of the caBIG program data context

- The group discussed and agreed upon the following categories of data that must be shared:
 - Clinomic
 - Genomic
 - Proteomic
 - Patient

Area 2 – Potential constraints to sharing of data and intellectual capital

- Confidence in the current technology:
 - Privacy of the data shared
 - Accuracy of the data shared
- Privacy concerned with publishing the data
- Determination of when the data should be published
- Issue – can not de-identify genomic data
- Issue – how to give credit to the primary investigator for the development of data in subsequent follow-on research.

Area 3 – What data needs to be shared

- Search for the “low hanging” fruit.
- Identify areas where data sharing is currently implemented, document success, and publish to cancer community.

What to share	Issues/Solutions Needed
1. Pre-publication data with IP (ICR)	<ul style="list-style-type: none">• Security issues• Technology confidence issues with privacy (i.e. will the data be handled in a manner that is not accessible by unauthorized individuals)• Technology confidence issues with accuracy (i.e. will the data that I submit, be sent accurately and not messed up during storage/etc)
2. Post publication (>500K NIH grant stands))	Authentication
3. Clinical Trials (CT) <ul style="list-style-type: none">• Note: Currently there is no mechanism	<ul style="list-style-type: none">• Patient Privacy• Is there a prototypical system that could be



What to share	Issues/Solutions Needed
<p>for sharing which clinical trials are available</p> <ul style="list-style-type: none">• Concept is to share all institutional trial information.• All open trials should be included as a starting point• Pharma Trials should be included as well• Variable Views should be available:<ul style="list-style-type: none">- Public view: should be available for the first release- Participating patients: should be made available in future releases, what is required for this view has yet to be determined- Referring physicians: should be available in future releases, what is required for this view has yet to be determined	<p>leveraged?</p>
<p>4. De-identified specimen and Tissue</p> <ul style="list-style-type: none">• Data in a virtual “tissue base” – the EDRN model	<ul style="list-style-type: none">• Setting up the systems and establishing the data exchanges is the most difficulty.• Mapping data elements, which are not consistent is difficulty.• Consistent annotations across all sites• Research evaluation management process may be required• Some sort of standardized material transfer program, licensing agreements (already available from (www.pcabc.upmc.edu))• Industry and pharma and biotech access issues

Area 4 – The need for industry collaboration

- Must address patent rights
- Must address Pharma/Privacy/Competitive issues e.g. research protocols
- Must recognize and address legal risks in private industry
- Issue – private industry will want to access data but may be hesitant in reciprocating
- Seek out and identify champions within pharma and research communities who will collaborate with data sharing initiatives



- Genomics companies understand the need to collaborate and share data and protocols but when the issue is vetted through their legal teams, they begin to close the possibility of data collaboration and sharing
- Must include pharma in the development models
- We must focus on and articulate the lost opportunities to industry due to a lack of data sharing
- AP4 – Academic Private Program – to be considered as a launching point for data sharing. These teams are already funded and working on the sharing of data.
- Must include the “boutiques” in the discussion as they provide a different perspective
- ATEP is a possibility for a communication vehicle for collaboration. Can be used to demonstrate the value of data sharing
- Must consider the FDA

Area 5 – Propose a cancer community cultural standard

- Issue – major cultural differences between business/pharma and research communities
- We must keep a focus on the centers, not just overall, due to the fact that the centers are already resource constrained.
- We should propose a standard on how to share data, who can see the data, and what they will see.
- Must share the data in a meaningful way.
- Must understand that in the current culture the primary investigator is driven to own their research data.
- NCI funded research should be public.
- Identified areas to research:
 - Pennsylvania Cancer Alliance
 - AP4
 - EDRN

Area 6 – Privacy issues and patient consent

- Can not de-identify genomic data
- Issue – data that can be shared is dependent upon the consent given by the patient
- Scope of patient consent is haphazard
- Wording of IRB consent forms needs to be standardized
- Can use HIPAA as a starting point, baseline but current scope of these consents is almost random. Therefore we may have a role in setting the levels of consent/authorizations

Area 7 – The identification and inclusion of additional caBIG participants

- The group identified the following entities to include as future participants in the scope of data sharing and intellectual capital:



- IRBs representation
- American Bar Association
- ILPA